

PATENTS  
AMS-002CIP CON

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Juan Carlos Parodi  
Serial No. : To Be Assigned  
Filed : Herewith  
For: : APPARATUS AND METHODS FOR REDUCING  
EMBOLIZATION DURING TREATMENT OF  
CAROTID ARTERY DISEASE  
Examiner : To Be Assigned  
Group Art Unit : 3763

Hon. Commissioner of Patents  
and Trademarks  
Washington, D.C. 20231

PRELIMINARY AMENDMENT

Sir:

Prior to examination of the above-identified application, please enter the following amendments:

In the Claims

Please cancel claims 4, 7, 16, and 17.

Please amend claims 1, 3, 5, 6, 9, 10, 12, 13, 15, and 19 as follows:

1. (Amended) Apparatus for removing emboli from the cerebral vasculature, the apparatus comprising:

a catheter having proximal and distal ends, a lumen extending therethrough, and a blood outlet port in communication with the lumen, the catheter having an outer

diameter sufficient to permit the catheter to be disposed in the cerebral vasculature;

a pear-shaped inflatable occlusion element disposed on the distal end of the catheter, the occlusion element having a contracted state suitable for transluminal insertion and an expanded state wherein the occlusion element occludes antegrade flow in the vessel, the occlusion element extending beyond the distal end of the catheter in the expanded state to form a tapered entrance to the lumen;

a venous return catheter having a proximal end with an inlet port and a distal end with an outlet port, and a lumen extending therebetween, the blood outlet port coupled to the inlet port of the venous return catheter.

3. (Amended) The apparatus of claim 1 further comprising a blood filter coupled between the blood outlet port and the inlet port of the venous return catheter.

5. (Amended) The apparatus of claim 1 wherein the occlusion element has a wall thickness that varies along the length of the occlusion element.

6. (Amended) The apparatus of claim 5 wherein a portion of the pear-shaped inflatable occlusion element extends beyond the distal end of the catheter in the contracted position and forms an atraumatic bumper.

9. (Amended) The apparatus of claim 2 wherein the catheter further comprises a second lumen through which the wire and inflatable balloon may be inserted.

10. (Amended) The apparatus of claim 1 further comprising a roller pump that engages the venous return

catheter to assist in drawing blood through the catheter and in reperfusing blood via the venous return catheter.

12. (Amended) A method for removing emboli from a vessel within the cerebral vasculature, the method comprising:

providing a catheter having proximal and distal ends, a lumen extending therethrough, an inflatable, pear-shaped occlusion element disposed on the distal end, a hemostatic port coupled to the lumen, and a blood outlet port coupled to the lumen, the occlusion element extending beyond the distal end of the catheter and forming a tapered entrance to the lumen when the occlusion element is expanded;

providing a venous return catheter having proximal end with an inlet port, a distal end with an outlet port, and a lumen extending therebetween;

inserting the distal end of the catheter into the cerebral vasculature to a position proximal to a treatment site;

inserting the distal end of the venous return catheter into a remote vein;

coupling the blood outlet port to the inlet port of the venous return catheter;

expanding the occlusion element to occlude antegrade flow through the vessel so that the occlusion element forms a tapered entrance to the lumen; and

causing blood to flow between the blood outlet port and the inlet port of the venous return catheter to induce reverse flow in, and remove emboli from, the vessel.

13. (Amended) The method of claim 12 further comprising:

providing a blood filter; and



AMENDMENTS - Version with markings to show changes made

In the Claims

1. (Amended) Apparatus for removing emboli from the cerebral vasculature [during an angioplasty or stenting procedure], the apparatus comprising:

a catheter having proximal and distal ends, a lumen extending therethrough, and a blood outlet port in communication with the lumen, the catheter having an outer diameter sufficient to permit the catheter [adapted] to be disposed in [a patient's carotid artery] the cerebral vasculature;

[an] a pear-shaped inflatable occlusion element disposed on the distal end of the catheter [and having an opening that communicates with the lumen], the occlusion element having a contracted state suitable for transluminal insertion and an expanded state wherein the occlusion element occludes antegrade flow in the vessel, the occlusion element extending beyond the distal end of the catheter in the expanded state to form a tapered entrance to the lumen;

a venous return catheter having a proximal end with an inlet port and a distal end[s] with an outlet port, and a lumen extending therebetween [therethrough, and a blood inlet port in communication with the lumen; and

tubing that couples], the blood outlet port coupled to the [blood] inlet port of the venous return catheter.

3. (Amended) The apparatus of claim 1 further comprising a blood filter coupled between the blood outlet port and the [blood] inlet port of the venous return catheter.

5. (Amended) The apparatus of claim 1 [4] wherein the [inflatable] occlusion element has [a pear-shape with] a wall thickness that varies along the length of the occlusion element [inflatable member].

6. (Amended) The apparatus of claim 5 [4] wherein a portion of the pear-shaped inflatable occlusion element [member] extends beyond the distal end of the catheter in the contracted position and forms an atraumatic bumper.

9. (Amended) The apparatus of claim 2 [1] wherein the catheter further comprises a second lumen through which the wire and inflatable balloon may be inserted.

10. (Amended) The apparatus of claim 1 further comprising a roller pump that engages the venous return catheter to assist in drawing [removes] blood through the catheter and in reperfusing [reperfuses] blood via the venous return catheter.

12. (Amended) A method for removing emboli from a vessel within the cerebral vasculature, the method comprising:

providing a catheter having proximal and distal ends, a lumen extending therethrough, an inflatable, pear-shaped occlusion element disposed on the distal end, a hemostatic port coupled to the lumen, and a blood outlet port coupled to the lumen, the occlusion element extending beyond the distal end of the catheter and forming a tapered entrance to the lumen when the occlusion element is expanded;

providing a venous return catheter having proximal end with an inlet port, a [and] distal end[s] with an outlet

port, and a lumen extending therebetween [therethrough, and a blood inlet port coupled to the lumen];

inserting the distal end of the catheter into the cerebral vasculature to a position proximal to a treatment site [the stenosis];

inserting the distal end of the venous return catheter into a remote vein;

coupling the blood outlet port to the inlet port of the venous return catheter;

[deploying] expanding the occlusion element to occlude antegrade flow through the vessel so that the occlusion element forms a tapered entrance to the lumen; and

causing blood to flow between the blood outlet port and the [blood] inlet port of the venous return catheter to induce reverse flow in, and remove emboli from, the vessel.

13.(Amended) The method of claim 12 further comprising:

providing a blood filter; and

coupling the blood filter in fluid communication between the blood outlet port and the [blood] inlet port of the venous return catheter.

15.(Amended) The method of claim 12 further comprising, while causing blood to flow between the blood outlet port and the [blood] inlet port, performing an interventional procedure with an interventional instrument inserted through the hemostatic port.

19.(Amended) The method of claim 12 further comprising:

providing a roller pump;

engaging the roller pump with the venous return  
catheter; and

actuating the pump to increase a rate of flow of  
blood between the blood outlet port and the [blood] inlet  
port.